United States Environmental Protection Agency | Office of Prevention, Pesticides And Toxic Substances (H-7508W) | EPA-738-R-93-004 June 1993

EPA R.E.D. FACTS

Biobor

Pesticide Reregistration

All pesticides sold or used in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for the active ingredients 2,2'-(1-methyltrimethylenedioxy)bis(4-methyl-1,3,2-dioxaborinane) and 2,2-oxybis(4,4,6-trimethyl-1,3,2-dioxaborinane), which comprise the reregistration case Biobor.

Use Profile

Biobor is a fungicide used in the fuel tanks and fuel lines of vehicles, farm equipment and industrial engines to prevent the growth of microbial organisms such as slime-forming bacteria and fungi, which could interfere with the unloading, use and quality of non-gasoline fuels. Biobor products are formulated as ready-to-use liquids.

Regulatory History

Biobor was initially registered as a pesticide in the United States in 1965. EPA required additional information regarding the health and environmental effects of Biobor during the Antimicrobial Data Call-IN issued in 1987, and through a second data call-in 1992.

Currently, six end use products are registered which contain the active ingredients include in the Biobor reregistration case.

Human Health Assessment

Toxicity

Biobor is of relatively low acute toxicity by the oral, dermal and inhalation routes of exposure; it has been placed in Toxicity Categories III

and IV (indicating the lowest degree of acute toxicity) for these effects. However, Biobor does produce severe irritation to the eyes, and is placed in Toxicity Category I (signaling a high degree of acute toxicity) for this effect.

Developmental toxicity studies using rats showed reduced fetal weights and reduced or incomplete ossification of parts of the skeleton. Studies in rabbits showed similar skeletal effects. However, Biobor no evidence of mutagenicity in a first-tier battery of studies.

Dietary Exposure

Boric acid esters, including Biobor, undergo rapid hydrolysis in the presence of water, forming boric acid or borate ion. These substances are essential to plant life, and small amounts are normally present in the human diet. Therefore, EPA does not anticipate that low levels of exposure to Biobor are associated with any significant degree of risk. Biobor is not registered for use on food, feed or processed commodities. Therefore, dietary exposure or risk is not expected.

Occupational and Residential Exposure

Minimal occupational exposure can be expected based on the currently registered uses of Biobor. A ready-to-use liquid which is added to fuel tanks, Biobor. A ready-to-use liquid which is added to fuel tanks, Biobor is available in one quart, five gallon, and 55 gallon sizes. Although there is the potential for minimal exposure while using the smaller sized containers of Biobor, use of a closed system metering pump is required by product labeling for delivery of the 55 gallon drum contents into large storage of fuel tanks.

Applicator Exposure

Biobor does not pose human dietary risks since no food-related uses are registered and dietary exposure is not anticipated.

A closed system must be used during application of large quantities of Biobor, and the chemicals generally are of low acute toxicity. Thus the risk to workers from exposure to Biobor is expected to be very low. Biobor can cause severe eye irritation. Therefore, to protect the eyes of mixers, loaders and applicators, product labeling will require the use of goggles and face shields. Animal studies using Biobor showed some developmental effects. However, there is little likelihood of a developmental toxicity risk to workers because Biobor's pattern of use results in minimal occupational exposure.

Environmental Assessment

Environmental Fate

Biobor is used inside fuel and oil storage tanks, and exposure to the environment should not result as long as Biobor products are used in accordance with approved label directions. EPA has required few environmental fate studies.

Ecological Effects

For the reasons discussed above, EPA is not requiring extensive ecotoxicity studies on Biobor products. The Agency is requiring acute toxicity studies on birds, fish and invertebrates, to characterize Biobor's acute toxicity to these species in case of accidents and to develop appropriate product labeling.

Ecological Effects Risk Assessment

EPA did not conduct a risk assessment for Biobor since it is registered only for use inside enclosed fuel containers. Exposure to the environment resulting from the use of this pesticide is expected to be negligible.

Additional Data Required

EPA is requiring product-specific data, including product chemistry and acute toxicity studies, as well as revised labelling for reregistration of pesticide products containing Biobor. Three confirmatory ecotoxicity studies also are required to develop appropriate environmental labeling precautions, for normal use situations and in case of accidents.

Product Labeling Changes Required

The labels of all registered pesticide products containing Biobor must comply with EPA's current pesticide labeling requirements. Additional labeling is also required to ensure the Federal Aviation Administration is consulted regarding the fuel additive use.

Technical Biobor is a severe eye irritant but because there are no EPA registered manufacturing-use products, changes to current labels do not apply. Changes to current product labeling may be made after the end-use product toxicology data have been submitted and reviewed.

Regulatory Conclusion

The use of currently registered pesticide products containing Biobor in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of products containing Biobor are eligible for reregistration.

These Biobor products will be reregistered once the required product-specific data and revised labeling are received and accepted by EPA. Products which contain other active ingredients in addition to Biobor will be eligible for reregistration only when all of their other active ingredients are also determined to be eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for Biobor during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field

Operations Division (H-7506C), Office of Pesticide Programs (OPP), U.S. EPA, Washington, D.C. 20460, telephone (703) 305-5805.

Following the comment period, the Biobor RED will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA. 22161, telephone (703) 487-4650.

For more information about Biobor or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (H-7508W), OPP, U.S. EPA, Washington, D.C. 20460, telephone 703-308-8000. For information about reregistration of individual products containing Biobor, please contact Marshall Swindell, Product Manager, Registration Division (H-7505C), OPP, U.S. EPA, Washington, D.C. 20460, telephone (703) 308-6908.

REREGISTRATION ELIGIBILITY DOCUMENT

BIOBOR

LIST C

CASE 3029

ENVIRONMENTAL·PROTECTION·AGENCY
OFFICE·OF·PESTICIDE·PROGRAMS
SPECIAL·REVIEW·AND·REREGISTRATION·DIVISION

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOEL	Lowest Observed Effect Level
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs

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EXECUTIVE SUMMARY

EPA has conducted a review of the scientific data base and other relevant information supporting the reregistration of Biobor and has determined that the data base is sufficient to allow the Agency to conduct a reasonable risk assessment. The Agency has completed its reregistration assessment of the available information on the pesticide active ingredients 2,2'-(1-methyltrimethylenedioxy)bis(4-methyl-1,3,2-dioxaborinane) and 2,2-oxybis(4,4,6-trimethyl-1,3,2-dioxaborinane), which comprise the chemical case Biobor. We have determined that the currently registered uses will not cause unreasonable risk to humans or the environment and that these uses and their products are eligible for reregistration.

Biobor is a fungicide for use in fuel tanks and in fuel lines. It is used to prevent microbial plant growth which might interfere with the unloading, use and quality of non-gasoline hydrocarbon fuels in vehicles, farm equipment, and industrial engines. Biobor products were initially registered in 1965.

Before reregistering the products containing Biobor, the Agency is requiring that product specific data and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. Also three confirmatory studies on ecotoxicity are required to indicate appropriate environmental precautionary labeling in case of product accidents. After reviewing these data and any revised labels and finding them acceptable, the Agency will reregister a product based on whether or not it meets the requirements in Section 3(c)(5) of FIFRA, that is whether product composition and labeling are acceptable and the product's uses will not cause unreasonable adverse effects to humans or the environment. Those products which contain other active ingredients will be eligible for reregistration only when the active ingredients in addition to Biobor are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products Section 4(g)(2)(B) or taking "other appropriate regulatory action," Sections 4(g)(2)(B) and 4(g)(2)(C). Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA Section 3(c)(5).

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of the active ingredients known as Biobor. The document consists of six sections. Section I is the introduction. Section II describes Biobor, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for Biobor. Section V discusses the reregistration requirements for Biobor. Finally, Section VI is the Appendices which support this Reregistration Eligibility Document. Additional details concerning the Agency's review of applicable data are available on request.[1]

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[1]EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

II. CASE OVERVIEW

A. Chemical Overview

The following two active ingredients are covered by this Reregistration Eligibility Document:

- **Chemical Name:** 2,2'-(1-methyltrimethylenedioxy) bis (4-methyl-1,3,2-dioxaborinane)
  - **Chemical Family:** Borate
  - **CAS Registry Number:** 2665-13-6
  - **OPP Chemical Code:** 012401
  - **Empirical Formula:** $C_{12}H_{24}B_2O_6$
  - **Trade and Other Names:** Biobor, Biobor JF, Borester
- **Chemical Name:** 2,2'-oxybis(4,4,6-trimethyl-1,3,2-dioxaborinane)
  - **Chemical Family:** Borate
  - **CAS Registry Number:** 14697-50-8
  - **OPP Chemical Code:** 012402
  - **Empirical Formula:** $C_{12}H_{24}B_2O_6$
  - **Trade and Other Names:** Biobor, Biobor JF, Borester

B. Use Profile

The following is information on the current registered uses of both active ingredients with an overview of the use sites, application methods, and product formulations. Appendix A contains a detailed description of the uses of **Biobor**.

TYPE OF PESTICIDE:	Microbicide/microbistat (slime-forming bacteria and fungi)
Use Sites:	indoor non-food: Fuels/Oil Storage Tank Bottom Water Additive (Preservatives)
Pests:	*Cladosporium resinae*, *Pseudomonas aeruginosa*, slime-forming bacteria and fungi
FORMULATION TYPES REGISTERED:	
Type:	End use
Form:	Ready to use liquid; formulated products contain both active ingredients
METHODS AND RATES OF APPLICATION:	
Types of treatment:	Preservative treatment
Equipment (not specified):	Metering pump
Timing:	Initial, Subsequent/maintenance, Shock/slug, Not specified
Rate of application:	
2,2'-(1-methyltrimethyl-enedioxy)bis(4-methyl-1, 3,2-dioxaborinane)	From 66 to 475 ppm (shock treatment) active ingredient by volume
2,2'-oxybis(4,4,6-trimethyl-1,3,2-dioxaborinane)	From 27 to 194 ppm (shock treatment) active ingredient by volume

Use Practices Limitations:	Do not apply directly to water. Do not pour into an empty tank.

C. Regulatory History

Pesticide products containing biobor were first registered in the United States in 1965 to the company U.S. Borax Research Corporation. There are currently six products registered to five companies. In 1987, the Agency required these companies to satisfy data requirements on these active ingredients as part of the Antimicrobial Data Call-In effort. The purpose of this was to have companies with antimicrobial pesticides generate and submit to the Agency applicable toxicology, and occupational exposure data which would be used for future risk assessments. Subsequently, the Agency issued another data call-in notice for additional data to these registrants in 1992 as part of the current reregistration program as described in the Introduction above.

Fuel treatment and fuel oil treatment have been the only registered pesticide uses for these chemicals. The Agency is not aware of any non-pesticidal uses for these compounds in the United States.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Biobor is a mixture of two borate compounds. Biobor is a yellow liquid with an aromatic odor. The chemical is insoluble in water, but is miscible in organic solvents.

a. Human Health Assessment

1. Toxicology Assessment

Boric acid esters, including Biobor, are known for their rapid hydrolysis in the presence of water to boric acid and the starting glycols, in this case butylene glycol and hexylene glycol. Since boric acid, or borate ion, is essential to plant life, small amounts are normally present in the human diet. Therefore, it is not anticipated that low levels of exposure to boric acid, borate ion, or organic esters of boric acid would be associated with any significant degree of risk. The data available on the toxicological effects of Biobor in laboratory animals are sufficient for assessing human risks.

a. Acute Toxicity

The acute toxicity of technical Biobor is relatively mild by the oral, dermal, or inhalation route (Toxicity Category 3 or 4). Biobor does not produce dermal irritation (Toxicity Category 4) and does not appear to induce any skin sensitization. It does, however, produce severe irritation to the eyes (Toxicity Category 1).

TEST	RESULT	CATEGORY
Oral LD_{50} rat	male: 3109 mg/kg. female: 3982 mg/kg. combined: 3460 mg/kg	III
Inhalation LC_{50} rat	> 5.18 mg/L	IV
Dermal LD_{50} rabbit	> 2020 mg/kg	III
Eye effects rabbit	irritation, corneal opacity	I
Skin effects rabbit	very slight irritation	IV
Skin sensitization - guinea pig	not sensitizing	

b. Developmental Toxicity

In a developmental toxicity study, rats were given, by gavage, 0, 100, 300, or 1,000 mg/kg/day of test substance in corn oil on gestation days 6-15. The maternal No Observed Effect Level (NOEL) was 300 mg/kg/day. The maternal toxicity (Lowest Observed Effect Level; LOEL) was 1,000 mg/kg/day on the basis of the reduced mean weight gain at termination of this study. This reduced weight gain may have been due to lower mean gravid uterine weight. The developmental toxicity NOEL was 100 mg/kg/day and the LOEL was 300 mg/kg/day. The LOEL was based on significantly reduced mean fetal weight and increased incidence of reduced or incomplete ossification of parts of the skeleton, including skull, vertebrae, and sternebrae.

In a developmental toxicity study in rabbits, Biobor was given by gavage at doses of 0, 25, 75, or 225 mg/kg/day of test substance in corn oil on gestation days 7-19. The maternal NOEL was 225 mg/kg/day, the highest dose tested. The developmental toxicity NOEL was 25 mg/kg/day, and the LOEL was 75 mg/kg/day. At 75 mg/kg/day, there were unossified or absent sternebrae, and higher dose levels produced a small or missing lung lobe, dilated renal pelvis, 26 presacral vertebrae, and missing cervical rib.

c. Mutagenicity

No evidence of mutagenicity was observed in an Ames test using five strains of Salmonella typhimurium, with or without metabolic activation. There was no evidence of a mutagenic effect in an in vivo mouse micronucleus assay. Confirmatory information for an unscheduled DNA synthesis study in rat hepatocytes is needed to clarify the cytotoxicity observed and justify the dose used.

2. Exposure Assessment

a. Dietary Exposure

There are no registered food uses for Biobor. The use of Biobor would not be expected to be associated with any dietary exposure or risks.

b. Occupational and Residential

Minimal occupational exposure can be expected based on the currently registered uses of this chemical. Biobor is formulated as a ready-to-use liquid (e.g., the product Diesel Doctor containing 3.1% of a.i. in a 4 fl. oz. bottle is added to a 10- to 26-gallon diesel fuel tank or to a large tank as fuel storage tank bottom water additive). Biobor is available in three container sizes: 1 quart, 5 gallons, and 55 gallons. Current product labels recommend "Choose the size that will be used up in a few treatments." Experience has shown that repeated opening and closing of containers for removal of small amounts of Biobor may lead to breakdown of the active ingredients and increase the potential for exposure; however, the exposure would be expected to be minimal. According to the label's recommendation, in order to deliver this chemical from a container (i.e., a 55-gallon drum) into the larger size storage tank, such as an aviation turbine fuel tank, a closed system metering pump should be used. Although there is a potential for dermal or inhalation exposure when the worker does the coupling and uncoupling of the pipelines, this type of exposure would be considered minimal since a closed system metering pump is used.

3. Risk Assessment

a. Occupational and Residential

Because a closed system is used for the application of Biobor, the dermal, inhalation, and eye exposure which may occur to workers during the repeated opening and closing of containers of Biobor and/or the coupling/uncoupling of pipelines from large fuel storage tanks is expected to be minimal. Consequently, the workers' risk via dermal or inhalation exposure are expected to be very low because of the expected minimal exposure and the generally low acute toxicity.

Technical Biobor has shown a high degree of eye irritation in the rabbit. However, whether or not eye protection for workers will be appropriate will depend upon results from required eye irritation studies on the formulated products.

Although Biobor was associated with incomplete ossification and/or unossification of several skeletal components in developmental studies in both the rat and rabbit, the likelihood of developmental toxicity risk to workers is not considered to be of concern, because Biobor's pattern of use would result in minimal occupational exposure. There is minimal risk for mutagenicity and its consequences (i.e. carcinogenicity) since Biobor was negative in a first-tier battery of mutagenicity tests (Ames and in vivo mouse micronucleus assay).

B. Environmental Assessment

1. Environmental Fate

Biobor is only used inside fuel/oil storage tanks and, therefore, it is expected that there will be minimal exposure to the environment when it is used according to the directions on the label. Limited information on hydrolysis indicates that the organic borate ester active ingredients are converted into boric acid and the corresponding glycols.

2. Ecological Effects

a. Ecological Effects Data

For the reason cited above, the Agency has not required extensive studies on ecotoxicology of these Biobor products. However, the Agency is requiring acute toxicity studies on birds, fish, and invertebrates. The Agency will use these data to characterize Biobor's acute toxicity to these non-target species in case of accidents and to determine appropriate environmental labeling for products. The fate of Biobor in the environment following engine combustion is not known at this time.

b. Ecological Effects Risk Assessment

The Agency has not conducted an ecological risk assessment for Biobor because its use is inside tanks. Exposure to the environment is expected to be negligible. The need for precautionary labeling statements will be determined after receipt and review of the ecotoxicity studies noted above.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient(s), whether products containing the active ingredient(s) are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing Biobor as the active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing Biobor. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of Biobor, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of Biobor and to determine that Biobor can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing Biobor as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Those products which contain active ingredients in addition to Biobor will be eligible for reregistration when the other active ingredients are determined to be eligible reregistration. Although the Agency has found that all uses of Biobor are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the reregistration of products containing Biobor, if new information comes to the Agency's attention or if the data requirements for reregistration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients Biobor and in consideration of its current use patterns of the products, the Agency has sufficient information on the health effects of Biobor. Therefore, the Agency concludes that all uses of products containing Biobor are eligible for reregistration.

The Agency has determined that Biobor products, labeled and used as specified in this Reregistration Eligibility Document, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

The Agency has determined that all uses specified in Appendix A for Biobor are eligible for reregistration.

B. Regulatory Position

Above, the Agency has concluded that the current uses of Biobor products are sufficiently supported by appropriate scientific studies and that their uses are not expected to cause unreasonable adverse risks to humans or the environment. For these reasons the Agency declares these uses and the registered products eligible for reregistration.

V. ACTIONS REQUIRED BY REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of end-use products. Currently there are no registered manufacturing-use products.

A. Generic Data Requirements

Registrants must submit the three acute ecotoxicity studies to characterize Biobor's toxicity to fish, birds, and aquatic invertebrates in case of an accident. This information was required in the 1992 data call-in notice and is due for the submission in September of 1993.

B. End-Use Products

1. Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not,

commit to conduct and submit new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers must be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in the Federal Register, Vol. 49, No. 188, Proposed Rules (1984). Please follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling. For those products designed for use in aviation fuel the following statement must be included on the label:

> "For use in aviation fuel, the Federal Aviation Admininstration must be consulted as to the acceptability of the additive for use in specific engines and/or aircraft".

VI. APPENDICES

APPENDIX A

Table of Use Patterns Subject to Reregistration

APPENDIX A - Case 3029, Chemical 012401 [2,2'-(1-Methyltrimethylenedioxy)bis(4,-methyl-1,3,2-dioxaborinane]

Application Type,	Application Timing,	Application Equipment,	Surface Type	Form	Minimum Application Rate (ppm ai by volume)	Maximum Application Rate (ppm ai by volume)	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations (also see Abbreviations)
USES ELIGIBLE FOR REREGISTRATION													
NONFOOD/NONFEED USES													
SITE Fuels/Oil Storage Tank Bottom Water Additive				**Use Group: Indoor Non-Food**									
Preservative Treatment, Initial, Metering Pump, Not Applicable				L-RTU	141 V	141 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Subsequent/maintenance, Metering Pump, Not Applicable				L-RTU	70 V	70 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Initial, Not on Label, Not Applicable				L-RTU	141 V	141 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Not on Label, Not on Label, Not Applicable				L-RTU	103 V	148 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Shock/slug, Not on Label, Not Applicable				L-RTU	309 V	475 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Subsequent/maintenance, Not on Label, Not Applicable				L-RTU	68 V	238 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Initial, Package Applicator, Not Applicable				L-RTU	132 V	132 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Subsequent/maintenance, Package Applicator, Not Applicable				L-RTU	66 V	66 V	NS	NS	NS	NS	NA	NA	A; B

Abbreviations used

Header: Max. # Apps. = Maximum number of applications; Max. # Apps. @ Max. Rate = Maximum number of applications at maximum rate; Min. Interval Between Apps. @ Max. Rate = Minimum interval of applications at maximum rate

In General: NS = Not Specified; NA = Not Applicable;

Form: L-RTU = Ready-to-use Liquid

Rate: ppm = parts per million; ai = active ingredient; V = calculated by volume

Limitations: Limitation A = Do not discharge effluent containing this product into lakes, streams, ponds, estauries, oceans, or public water. Limitation B = Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment authority.

APPENDIX A - Case 3029, Chemical 012402 [2,2'-Oxybis(4,4,6-trimethyl-1,3,2-dioxaborinane]

Application Type, Application Timing, Application Equipment, Surface Type	Form	Minimum Application Rate (ai by volume)	Maximum Application Rate (ai by volume)	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations (also see Abbreviations)
USES ELIGIBLE FOR REREGISTRATION										
NONFOOD/NONFEED USES										
SITE Fuels/Oil Storage Tank Bottom Water Additive									**Use Group: Indoor Non-Food**	
Preservative Treatment, Initial, Metering Pump, Not Applicable	L-RTU	57 V	57 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Subsequent/maintenance, Metering Pump, Not Applicable	L-RTU	29 V	29 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Initial, Not on Label, Not Applicable	L-RTU	57 V	57 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Not on Label, Not on Label, Not Applicable	L-RTU	42 V	60 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Shock/slug, Not on Label, Not Applicable	L-RTU	125 V	194 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Subsequent/maintenance, Not on Label, Not Applicable	L-RTU	27 V	97 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Initial, Package Applicator, Not Applicable	L-RTU	54 V	54 V	NS	NS	NS	NS	NA	NA	A; B
Preservative Treatment, Subsequent/maintenance, Package Applicator, Not Applicable	L-RTU	27 V	27 V	NS	NS	NS	NS	NA	NA	A; B

Abbreviations used

Header: Max. # Apps. = Maximum number of applications; Max. # Apps. @ Max. Rate = Maximum number of applications at maximum rate; Min. Interval Between Apps. @ Max. Rate = Minimum interval of applications at maximum rate

In General: NS = Not Specified; NA = Not Applicable;

Form: L-RTU = Ready-to-use Liquid

Rate: ppm = parts per million; ai = active ingredient; V = calculated by volume

Limitations: Limitation A = Do not discharge effluent containing this product into lakes, streams, ponds, estauries, oceans, or public water. Limitation B = Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment authority.

APPENDIX B

Table of The Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for oxalic acid covered by this Reregistration Eligibility document. It contains generic data requirements that apply to oxalic acid in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical.
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Biobor

PRODUCT CHEMISTRY		USE	BIBLIOGRAPHIC CITATION
61-1	Chemical Identity	M	MRID 41984001,42004701
61-2(a)	Beginning Materials and Manuf Process	M	MRID 41984001,42004701
61-2(b)	Formation of Impurities	M	MRID 41984001,42004701
62-1	Preliminary Analysis	M	MRID 41984002,41984101
62-2	Certified Limits	M	MRID 41984002,41984101
62-3	Analytical Methods	M	MRID 41984002,41984101
63-2	Color	M	MRID 42023501,42011401
63-3	Physical State	M	MRID 42023501,42011401
63-4	Odor	M	MRID 42023501,42011401
63-5	Melting Point	M	MRID 42023501,42011401
63-6	Boiling Point	M	MRID 42023501,42011401
63-7	Density	M	MRID 42023501,42011401
63-8	Solubility	M	MRID 42023501,42011401
63-10	Dissociation Constant	M	MRID 42023501,42011401
63-11	Octanol/Water Partition Coefficient	M	MRID 42023501,42011401
63-12	pH	M	MRID 42023501,42011401
63-13	Stability	M	MRID 42023501,42011401

ENVIRONMENTAL FATE

EPA waived 40 CFR Part 158 generic data requirements for reasons discussed in Section III.

TOXICOLOGY

EPA imposed 40 CFR Part 158 generic data requirements in the Anti-Microbial Data Call-In.

OCCUPATIONAL EXPOSURE

EPA waived 40 CFR Part 158 generic data requirements for reasons discussed in Section III.

ECOLOGICAL EFFECTS

EPA imposed 40 CFR Part 158 generic data requirements in the Anti-Microbial Data Call-In.

APPENDIX C

Citations Considered to be Part of the Data Base Supporting the Reregistration of Biobor

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears

as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

BIBLIOGRAPHY

MRID	CITATION
41136601	Lawlor, T. (1989) Mutagenicity Test on Biobor JF in the Ames Salmonella/Microsome Reverse Mutation Assay: HLA Study No. 10630-0-401. Unpublished study prepared by Hazleton Laboratories America, Inc. 35 p.
41136602	Cifone, M. (1989) Mutagenicity Test on Biobor JF in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay: HLA Study No. 106300-447. Unpublished study prepared by Hazleton Laboratories America, Inc. 28 p.
41136603	Ivett, J. (1989) Mutagenicity Test on Biobor JF in the in vivo Mouse Micronucleus Assay: HLA Study No. 10630-0-455. Unpublished study prepared by Hazleton Laboratories America, Inc. 23 p.
41528001	Harbell, J. (1988) Mouse Lymphoma Mutagenesis Assay: Biobor: Lab Project Number: NO1-CP-41004. Unpublished study prepared by Microbiological Associates, Inc. 26 p.
41579701	Lemen, J. (1990) Rabbit Teratology Study with Biobor JF: HLA Study No.: 182-131. Unpublished study prepared by Hazleton Laboratories America, Inc. 179 p.
41579702	Lemen, J. (1990) Rat Teratology Study with Biobor JF: HLA Study No.: 182-129. Unpublished study prepared by Hazleton Laboratories America, Inc. 300 p.
41726901	Kelley, J. (1990) Phase 3 Abbreviated Summary of MRID 41378101: 13-Week Dermal Toxicity Study in Rabbits with Biobor JF: HLA Study No. 182-133. Unpublished study prepared by Hazleton Laboratories America, Inc. 16 p.
41726902	Kelley, J. (1990) Phase 3 Abbreviated Summary of MRID 41579702: Rat Teratology Study with Biobor JF: HLA Study No. 182-129. Unpublished study prepared by Hazleton Laboratories America, Inc. 28 p.
41726903	Kelley, J. (1990) Phase 3 Abbreviated Summary of MRID 41579701: Rabbit Teratology Study with Biobor JF: HLA Study No. 182-131. Unpublished study prepared by Hazleton Laboratories America, Inc. 25 p.
41872401	Lemen, J. (1991) Rabbit Teratology Study with Biobor JF: Addendum to Final Report: Lab Project Number: 182-131. Unpublished study prepared by Hazleton Laboratories America, Inc. 10 p.
41872402	Lemen, J. (1991) Rat Teratology Study with Biobor JF: Addendum to Final Report: Lab Project Number: 182-129. Unpublished study prepared by Hazleton Laboratories America, Inc. 9 p.
41941901	Kukulinski, M. (1991) Acute Dermal Toxicity : Diesel Stabil: Final Report: Lab Project Number: 90-325-4.

Unpublished study prepared by Tox Monitor Labs. 9 p.

41941902 Kukulinski, M. (1991) Acute Oral Toxicity: Diesel Stabil: Final Report: Lab Project Number: 90-325-3. Unpublished study prepared by Tox Monitor Labs. 9 p.

41941903 Kukulinski, M. (1990) Dermal Sensitization Study of Diesel Stabil in Albino Guinea Pigs (Modified Buehler Test): Lab Project Number: 026-001. Unpublished study prepared by Biological Safety Research, Inc. 16 p.

41941904 Kukulinski, M. (1990) Primary Dermal Irritation Study: Diesel Stabil: Final Report: Lab Project Number: 90-325. Unpublished study prepared Tox Monitor Labs. 8 p.

41941905 Kukulinski, M. (1990) Primary Eye Irritation Study: Diesel Stabil: Final Report: Lab Project Number: 90-325. Unpublished study prepared by Monitor Labs. 15 p.

41972601 Kuhn, J. (1991) Acute Oral Toxicity Study in Rats: Biobor JF: Lab Project Number: 7689-90. Unpublished study prepared by Stillmeadow, Inc. 24 p.

41972602 Kuhn, J. (1991) Acute Dermal Toxicity Study in Rabbits: Biobor JF: Lab Project Number: 7690/90. Unpublished study prepared by Stillmeadow, Inc. 13 p.

41972603 Holbert, M. (1991) Acute Inhalation Toxicity Study in Rats: Biobor JF: Lab Project Number: 7691-90. Unpublished study prepared by Stillmeadow, Inc. 19 p.

41972604 Kuhn, J. (1991) Primary Dermal Irritation Study in Rabbits: Biobor JF: Lab Project Number: 7693-90. Unpublished study prepared by Stillmeadow, Inc. 13 p.

41972605 Kuhn, J. (1991) Dermal Sensitization Study in Guinea Pigs: Biobor JF: Lab Project Number: 7694-90. Unpublished study prepared by Stillmeadow, Inc. 21 p.

41972701 Kuhn, J. (1991) Acute Oral Toxicity Study in Rats: Biobor JF: Lab Project Number: 7689/90. Unpublished study prepared by Stillmeadow, Inc. 24 p.

41972702 Kuhn, J. (1991) Acute Dermal Toxicity Study in Rabbits: Biobor JF: Lab Project Number: 7690-90. Unpublished study prepared by Stillmeadow, Inc. 13 p.

41972703 Holbert, M. (1991) Acute Inhalation Toxicity Study in Rats: Biobor JF: Lab Project Number: 7691/90. Unpublished study prepared by Stillmeadow, Inc. 19 p.

41972704 Kuhn, J. (1991) Primary Dermal Irritation Study in Rabbits: Biobor JF: Lab Project Number: 7693/90. Unpublished study prepared by Stillmeadow, Inc. 13 p.

41972705 Kuhn, J. (1991) Dermal Sensitization Study in Guinea Pigs: Biobor JF: Lab Project Number: 7694-90. Unpublished study prepared by Stillmeadow, Inc. 21 p.

41984001 United States Borax and Chemical Corp. (1991) Product Chemistry for Biobor JF. Unpublished study. 147 p

41984002 United States Borax and Chemical Corp. (1991) Product Chemistry for Biobor JF. Unpublished study. 9 p.

41984101 United States Borax and Chemical Co. (1991) Product Chemistry for Biobor JF. Unpublished study. 9 p.

42004701 United States Borax and Chemical Corp. (1991) Product Chemistry for Biobor JF. Unpublished study. 147 p.

42023501 U.S. Borax and Chemical Corp. (1991) Product Chemistry for Biobar JF. Unpublished study. 86 p.

42086101 Kuhn, J. (1991) Primary Eye Irritation Study in Rabbits: Lab Project Number: 7692-90. Unpublished study prepared by Stillmeadow Labs, Inc. 22 p.

42086201 Kuhn, J. (1991) Primary Eye Irritation Study in Rabbits: Biobor JF: Lab Project Number 7692-90. Unpublished study prepared by Stillmeadow Labs, Inc. 22 p.

42396601 Harrison, E. (1992) Diesel STA BIL: Product Identity and Composition. Unpublished study prepared by Gold Eagle Co. 37 p.

42396602 Harrison, E. (1992) Diesel STA BIL: Analysis and Certification of Product Ingredients. Unpublished study prepared by Gold Eagle Co. 9 p.

42396603 Anthony, C. (1992) Gold Eagle Diesel STA-BIL: Physical and Chemical Properties: Lab Project Number: 00367-001. Unpublished study prepared by Case Consulting Laboratories, Inc. 50 p.

APPENDIX D
List of Available Related Documents

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE,"** all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient Statements must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

Anne E. Lindsay

Anne E. Lindsay, Director
Registration Division (H-7505

APPENDIX E

Pesticide Reregistration Handbook
PR Notices 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

PR NOTICE 86-5

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations

specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

- INDEX-

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A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,.... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE.** An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

+Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

+Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____
Name Signature

Company Name: _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 This cross reference number is used in the study in place of the following words or phrase at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE	LINE	REASON FOR THE DELETION	FIFRA REFERENCE
6	14	Identity of Inert Ingredient	§10(d)(1)(C)
12	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 This cross reference number noted on a place-holder page is used in place of the following whole pages at the indicated volume and page references.

DELETED PAGE(S): are attached immediately behind this page.

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Study Director _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

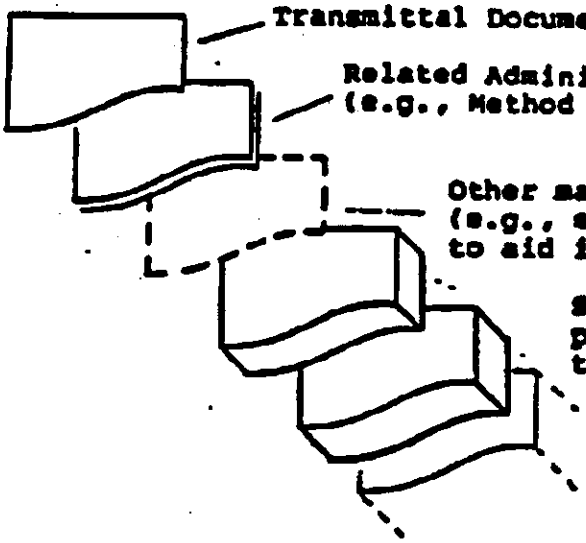
Example 3.

The submltter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

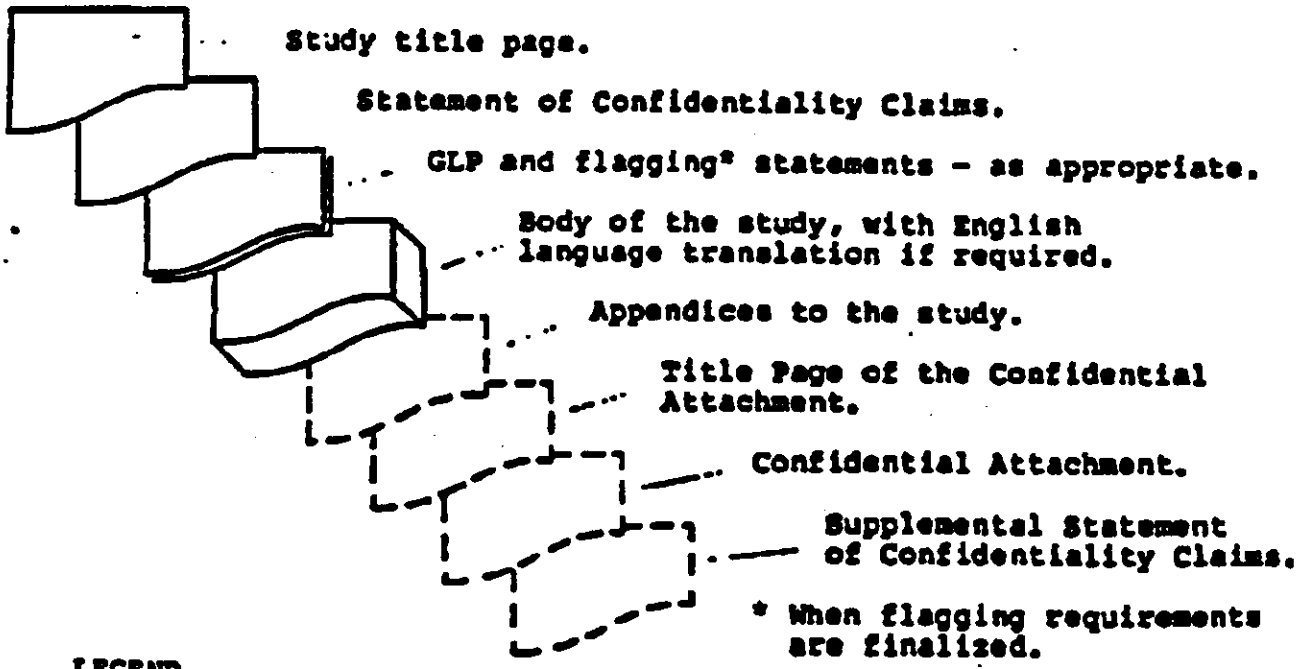
Submitter_____

ATTACHMENT 7.

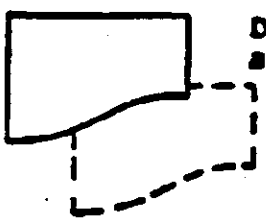
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



APPENDIX F

Generic Data Call-In

For Case 3029, Biobor, no Generic Data Call-In will be issued.

APPENDIX G

Product Specific Data Call-In

Attachment A

Chemical Status Sheet

BIOBOR: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing biobor.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of oxalic acid. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment B), (3) the Requirements Status and Registrant's Form (Attachment C), (4) a list of registrants receiving this DCI (Attachment D), (5) the EPA Acceptance Criteria (Attachment E), and (6) the Cost Share and Data Compensation Forms in replying to this Oxalic Acid Generic Data Call-In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the Product Specific database for biobor are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional data on biobor are needed. These data are needed to fully complete the reregistration of all products containing biobor.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the Product Specific data requirements and procedures established by this Notice, please contact Marshall Swindell at (703) 305-6908.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Marshall Swindell, Chemical Review Manager
Antimicrobial Product Branch
Registration Division (H7505-C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Biobor PDCI

ATTACHMENT B

PRODUCT SPECIFIC DATA CALL-IN RESPONSE FORMS (Form A) PLUS INSTRUCTIONS

INSTRUCTIONS FOR COMPLETING THE "DATA CALL-IN RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-4. Already completed by EPA.

Item 5. If you wish to voluntarily cancel your product, answer "yes". If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is identical to another product and you qualify for a data exemption, you must respond with "yes" to Item 7a (MUP) or 7B (EUP) on this form, provide the EPA reregistration numbers of your source (s); you would not complete the requirements status and registrant's response" form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

Item 7a. For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes." if you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver. See item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

ATTACHMENT B

PRODUCT SPECIFIC DATA CALL-IN RESPONSE FORMS (Form A) PLUS INSTRUCTIONS

INSTRUCTIONS FOR COMPLETING THE "DATA CALL-IN RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-4. Already completed by EPA.

Item 5. If you wish to voluntarily cancel your product, answer "yes". If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is identical to another product and you qualify for a data exemption, you must respond with "yes" to Item 7a (MUP) or 7B (EUP) on this form, provide the EPA reregistration numbers of your source (s); you would not complete the requirements status and registrant's response" form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

Item 7a. For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes." if you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver. See item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

ATTACHMENT C

PRODUCT SPECIFIC REQUIREMENT STATUS AND REGISTRANT'S RESPONSE FORMS (Form B) PLUS INSTRUCTIONS

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-3. Completed by EPA. Note the unique identifier number assigned by EPA in item 3. This number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. The guidelines reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use patters (s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/ or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on 8 months after issuance of the Reregistration Eligibility Documents unless EPA determines that a longer time period is necessary.

Item 9. Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table. Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice.

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available on for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this notice that my product is similar. Enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required

data; if the required study is not submitted on time, my product my be subject to suspension.

3. I have made offers to share in the cost to develop data (Offers to Cost Share). I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed " Certification of offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the require data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (submitting an Existing Study). I certify that this study will meet all the requirements for submittal of existing data outlined in option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgrade (upgrading a study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this Option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s) number (s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registratrant's data, I will submit a completed "Certification With Respect To Data Compensation

Requirements" form.

7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be require to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status chosen. I also understand that the deadline for submission of data as specified by the original data cal-in notice will not change.

Items 10-13. Self-explanatory.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

ATTACHMENT D

EPA GROUPING OF END-USE PRODUCTS FOR MEETING DATA REQUIREMENTS FOR REREGISTRATION

EPA'S BATCHING OF 2,2'-(1-methyltrimethylenedioxy)bis(4-methyl-1,3,2-dioxaborinane) and 2,2'-oxybis(4,4,6-trimethyl-1,3,2-dioxaborinane) FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of end-use products containing the active ingredients 2,2'-(1-methyltrimethylenedioxy)bis(4-methyl-1,3,2-dioxaborinane) and 2,2'-oxybis(4,4,6-trimethyl-1,3,2-dioxaborinane), in combination referred to as Biobor, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Batching has been accomplished using the readily available information described above, and frequently acute toxicity data on individual end-use products has been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual end-use product should the need arise.

Registrants of end-use products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide

the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Only six products contain 2,2'-(1-methyltrimethylenedioxy) bis(4-methyl-1,3,2-dioxaborinane) and 2,2'-oxybis(4,4,6-trimethyl-1,3,2-dioxaborinane) as the active ingredients. The products have been placed into two batches in accordance with the active and inert ingredients, type of formulation and labeling. The following data tables identify the products in each batch.

BIOBOR BATCHING

Batch	EPA Reg. No.	2,2'-Oxybis(4,4,6-trimethyl-1,3,2 dioxaborinane	2,2'-(1-Methyltrimethylenedioxy)bis(4-methyl-1,3,2-dioxaborinane)	Formulation Type
1	5009-37	27.4%	67.6%	liq
	55250-1	27.4%	67.6%	liq
	65217-1	27.4%	67.6%	liq
2	47099-2	2.7%	6.6%	liq
	57125-10	3.1%	7.6%	liq
	57125-11	3.2%	7.9%	liq

ATTACHMENT E

EPA ACCEPTANCE CRITERIA

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at <0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered; for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.
- ____ Statement of whether batch or continuous process.
- ____ Relative amounts of beginning materials and order in which they are added.
- ____ Description of equipment.
- ____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
- ____ Statement of whether process involves intended chemical reactions.
- ____ Flow chart with chemical equations for each intended chemical reaction.
- ____ Duration of each step of process.
- ____ Description of purification procedures.
- ____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at $\geq$ 0.1%.
2.____ Degree of accountability or closure $\geq$ ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at $\geq$ 0.1% and for certain toxicologically significant impurities at <0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color

____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State

____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor

____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point

____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point

____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity

____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility

____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure

____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant

____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient

____ Measured at about 20-25° C
____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH

____ Measured at about 20-25° C
____ Measured following dilution or dispersion in distilled water

63-13 Stability

____ Sensitivity to metal ions and metal determined
____ Stability at normal and elevated temperatures
____ Sensitivity to sunlight determined

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4.*___ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 μm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C ($\pm$2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.___ One of the following methods is utilized:
   _____ Freund's complete adjuvant test
   _____ Guinea pig maximization test
   _____ Split adjuvant technique
   _____ Buehler test
   _____ Open epicutaneous test
   _____ Mauer optimization test
   _____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*__ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

ATTACHMENT F

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

United States Environmental Protection Agency
Washington, D. C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 3029 Biobor (*)

Co. Nr.	Company Name	Additional Name	Address	City & State	Zip
005009	PETROLITE CORPORATION		369 MARSHALL AVENUE	ST LOUIS MO	63119
035559	GOLD EAGLE CO.		4400 SO. KILDARE	CHICAGO IL	60632
047099	PARKER-HANNIFIN CORPORATION	RACOR IVISION	BOX 3208	MODESTO CA	95353
055250	AMALGAMATED COAL & PETROLEUM SPECI		BOX 9798	FT WAYNE IN	46899
057125	DIAL CORPORATION	TECHNI..AL CENTER	15101 NORTH SCOTTSDALE ROAD	SCOTTSDALE AZ	85254
065217	HAMMONDS FUEL ADDITIVES, INC.		BOX 38114-0407	HOUSTON TX	77238

ATTACHMENT G

COST SHARE AND DATA COMPENSATION FORMS

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	Company Number
Chemical Name	**EPA Chemical Number**

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification.

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 3-31-(

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0105), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

   [ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form."

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form